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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,756	12/21/2005	Richard E Musty	B0192.70062US00	1614

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
12/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,756	MUSTY ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,18,19 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 18-19 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 14, 18-19, 22-28 are pending and under examination herein.

Response to Arguments

Applicants argue that Brooke et al. does not disclose that CBC (cannabichromene) or CBC-V (cannabichromene propyl analogue) is present in more than 30% of the cannabinoids of the composition as is now claimed in the amended claims. Applicants refer back to the Whittle Declaration and argue that the level of CBC is very low in mature plants and is lower than the claimed amount. Applicants argue that absent a specific teaching to specific cannabinoids, the skilled person would not have known which cannabinoids would be useful in treating mood disorders. Applicants argue over the second 35 USC 103 rejection over Whittle that Whittle does not link any specific cannabinoid to the treatment of depression and does not disclose that CBC is present in more than 30% of the cannabinoids of the composition. Applicants argue that there are dozens of cannibinoids known in cannabis and that absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one of the cannabinoids would be useful in treating mood disorders.

In response to the above arguments, it is noted that the Brooke et al. reference was not used for teaching any amounts of cannabichromene. Brooke et al. was used for the general teaching that medicinal uses for the active ingredients of cannabis are known. The active ingredients of cannabis include CBC, which is one of the four ingredients listed. The medicinal uses include stress and depression. It is understood

that Applicants argue that mature plants do not contains amounts of CBC higher than 30% (as currently claimed). However, it is still the view of the Examiner that there may be certain plants that do not contain high amounts of CBC but there are plants that contain higher amounts of CBC as pointed out in previous responses (referring to the articles of Harvey et al. and Turner et al.). Because there are teachings that CBC is an active ingredient of cannabis that is useful for treating mood disorders such as stress and depression, and there is evidence that CBC occurs in abundant amounts in plants, the present invention is still deemed obvious.

Regarding the Double Patenting rejection, Applicants assert that because the present claims have been amended to recite CBC and the claims of Application 11/760,364 recite CBG, the two inventions are not obvious because they use two different compounds. This argument is not found persuasive because as stated in the rejection, both applications teach methods of treating a mood disorder with a naturally occurring cannabinoid.

Please see the following modified rejections due to Applicants amendments.

Claim Rejections – 35 U.S.C. § 112

Claim 14 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim recites a method for treating a mood disorder in a

human patient by administering CBC and/or CBC-V wherein the CBC and/or CBC-V is substantially pure or is an extract from a cannabis plant that contains greater than or equal to 30% CBC and/or CBC-V of the total cannabinoid content. The specification provides support for the cannabis plant extract to contain 30% of the total cannabinoid content as CBC. The extract amount of 30% is defined in relation to the CBC and not the CBC-V.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 18-19, 22-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,51) and Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Brooke et al. teach that medicinal uses, such as depression, have been found for the active ingredients of cannabis, including cannabichromenes (meeting the limitation of claims 14-15; Col. 1, lines 23-33).

Brooke et al. does not teach that the cannabichromene compound is an extract of a cannabis plant that contains greater than or equal to 30% CBC, CBC-V, or the route of administration.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds. Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction). Turner et al. further teach that THC and CBC are the major cannabinoids in freshly harvested drug-type cannabis material (see page 285S, first full paragraph).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression. It would have further been obvious to use the cannabichromene composition taught by Travis and Turner et al. to treat depression, because Travis and Turner et al. teach cannabichromene compositions that are useful as pharmaceutical compositions. One would have been motivated to use the cannabichromene compositions taught by Travis and Turner et al. to treat depression with a reasonable expectation of success because Brooke et al. teaches that cannabichromenes show medicinal use in treating depression. It would further be obvious that the CBC amount would be higher because of the teachings of Turner that CBC is the major cannabinoid in freshly harvested drug-type cannabis material, which would make the amount of 30% obvious.

Claims 14, 18-19, 22-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle and al. (US Pg/Pub 2005/0042172) in view of Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Whittle et al. teaches therapeutic compositions that are inhaled as a vapour (paragraph 0030) that comprise one or more natural or synthetic cannabinoids, which includes cannabichromene (paragraphs 0049 and 0051). It is further taught that the compositions that contain natural cannabinoids which are derived from cannabis plants (paragraphs 0042, 0043 0053). The compositions are taught to comprise carriers or solvents (paragraph 0072). The compositions are used in methods of treating inflammatory pain particularly that associated with depression (paragraph 0056), in which it is considered that the composition would necessarily be treating depression.

Whittle et al. does not teach that the CBC extract from the cannabis plant contains greater than or equal to 30% CBC of the total cannabinoid content.

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction). Turner et al. further teach that THC and CBC are the major cannabinoids in freshly harvested drug-type cannabis material (see page 285S, first full paragraph).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Whittle et al. that cannabichromenes are useful in treating such disorders as pain associated with

depression. One would have been motivated to use cannabichromene to treat depression with a reasonable expectation of success because Whittle et al. teaches that cannabichromenes show medicinal use in treating pain associated with depression, which would necessarily treat depression. Further, Turner teaches that CBC is one of the most abundant naturally occurring cannabinoids; therefore, it would be obvious that the content of CBC would be higher to treat a mood disorder.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim s 14-15, 18-25, 27-28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 12, 14 of copending Application No. 11/760,364. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both applications teach methods of treating a mood disorder with a naturally occurring cannabinoid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627